

Frances J.R. Richmond

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Education/Nationality

1973 BNSc, Queen's University, Kingston, Canada
1974 MSc, Physiology, Queen's University, Kingston, Canada
1976 PhD, Neurophysiology, Queen's University, Kingston, Canada
1988 ndc, National Defence College, Canada
*born in Canada; currently holding US and Canadian citizenship

Honours/Awards

1969 John Thorburn Scholarship; Ontario Scholarship; 100th Anniversary
Scholarship
1970 Susan Near Scholarship in Psychology
1972 W.B. Saunders Book Prize
1973 Queen's University Medal in Nursing
Studentship - Medical Research Council of Canada
1977-1978 Fellowship - Medical Research Council of Canada
1979 Scholarship - Medical Research Council of Canada
Research Associateship - Killam Foundation, (awarded but declined)
1987 Basmajian Award for Excellence in Research
2012 TOPRA Award for Excellence in Education

Professional Experience/Academic Appointments

1973-1976 Demonstrator, Physiology 210, 312, 510, 474/874,
Department of Physiology, Queen's University,
Kingston, Ontario
1976-1978 Lecturer, Department of Physiology, Queen's University,
Kingston, Ontario
MRC Postdoctoral Fellow, NIDR, National Institutes of Health,
Bethesda, Maryland, U.S.A.
MRC Postdoctoral Fellow, Département de Physiologie,
Université de Montréal, Montréal, P.Q.
1979-1983 Assistant Professor and MRC Scholar, Department of Physiology,
Queen's University, Kingston, Ontario

- 1983-1984 Associate Professor and MRC Scholar
- 1984-1987 Associate Professor
- 1987-1999 Full Professor
- 1988-1990 Associate Dean, Life Sciences, Faculty of Medicine, Queen's University
- 1990-1995 Member, MRC Group in Sensory-Motor Physiology
- 1990-1996 Member, Networks of Centres of Excellence, Neural Regeneration and Functional Repair
- 1993-1994 Visiting Scholar seconded as Policy Analyst, Industry Canada
- 1994-1995 Clinical Research Scientist, Alfred E. Mann Foundation for Scientific Research, Sylmar, CA. (sabbatical appointment)
- 1995-2000 Director, MRC Group in Sensory-Motor Neuroscience;
Preclinical and Clinical Trials Consultant, Advanced Bionics Corp., Sylmar, CA
- 2000-2008 Professor, School of Pharmacy;
Director, Regulatory Science Master's Program, USC;
Director, Regulatory and Clinical Science, Alfred E Mann Institute for Biomedical Engineering
Cross-appointed as Professor, Cell and Neurobiology
- 2008-2017 Professor, Titus Family Department of Clinical Pharmacy and Pharmacoeconomics and Policy;
Director, Regulatory Science Programs, USC School of Pharmacy
- 2010-2015 Director, Regulatory Knowledge and Support Group, LA Basin Clinical and Translational Science Institute
- 2011-2017 Director, International Center for Regulatory Science at USC
Adjunct Professor of Health Economics and Policy, TJAB
- 2017-2020 Professor and Chair, Department of Regulatory and Quality Sciences
USC School of Pharmacy
- 2020-present Professor and Director, DK Kim International Center for Regulatory Science at USC
Director, USC-APEC Center of Excellence, Medical Devices

Teaching Activities at Queen's University

- Physiology 474/874 - Mammalian Neurophysiology; course supervisor/lecturer
4th year honours life sciences and graduate students.
- Physiology 312/510 - Vertebrate Physiology
3rd year honours life sciences and first year medical students.
- Phase I - Medicine - first year - 5 lectures and 3 lab demonstrations
- Physiology 210 - Mammalian Physiology –
Primarily nursing, rehabilitation therapy and physical education students
- Physiology 320 - Mammalian Neuroscience - 3rd year life sciences students
- Human Pathophysiology - Special lecture series; 10 lectures to engineering and research
staff of A.E. Mann Foundation and Advanced Bionics Corporation, 1994-1995.
- Physiology 434 - Advanced Physiology
1990, 1992, 1995, 1996 - 1 project student
- Physiology 884 - Graduate Student lab course 1996, 1997
- Physiology 801 - Beyond Academia (graduate course)
(enrollment: 25) 1996, 1997, 1998

Teaching Activities at USC - Outside Regulatory Science Program

- Pharmacy 309 – Biological Sciences I- 4-6 hours either on sensorimotor neuroscience
or embryology, 2000-2004
- Pharmacy 406 – Pharmaceutics IV- 2 hours on regulatory management of new drugs
2000-2003
- Biomedical Engineering 416- Development and Regulation of Medical Products
1999-2004 – co-supervisor
2005-present, 3-4 afternoons
- Molecular Pharmacology and Toxicology 501- 2 hours, industrial toxicology
2000-2002
- Molecular Pharmacology and Toxicology 603- Signal Transduction
2000 course supervisor

BISC 406L- Biotechnology 2001 lecturer,
2008 to present, 3 hours, FDA regulation

Pharmacy 670 Marketing and Development in the Pharmaceutical Industry
2010 to 2015, coorganizer and speaker.

Pharmacy 508 Pharmacy Literature Analysis and Drug Information
2010 to 2018, 2 hours X2

Pharmacy 510 Pharmacy Practice and Experience II
2010 to 2018 2 hours

CPTX 609 Preclinical Experimental Therapeutic Drug Development
2011 to 2018, 2 hours

BME 201 Biomedical Engineering Practice
2013 to 2021 3 hours

Teaching Activities at USC -In Regulatory Science Program

All of these courses are part of Regulatory Science offerings and are team taught; participation and role varies with year and need but I typically was involved with design and initial development in the early years of each course and participate in at least a lecturing capacity in most for reasons of continuity and quality assurance. Courses managed as primary instructor in 2020-21 are underlined, a few are given 2 or three times each year.

RXRS 416 - Medical Products from Idea to Market

MPTX 511 - Introduction to Regulation

MPTX 512 - Regulation of Drugs and Biologics

MPTX 513 - Regulation of Medical Devices and Diagnostics

MPTX 514 - Regulation of Foods and Dietary Supplements

MPTX 515 - Quality Systems and Standards

MPTX 516 - Medical Products and the Law

MPTX 517 - Structure and Management of Clinical trials

MPTX 630 - Internship

MPTX 518 - Writing Regulatory Submissions

MPTX 519 - International Regulation

MPTX 521 - Seminar program

MPTX 522 - Clinical Trial Design

MPTX 602 - Science, Research and Ethics

RSCI 508 Quality systems for Drugs

RSCI 509 Quality Systems for Devices

RSCI 520 - Risk Management Theory

RSCI 527 - Medical Product Safety
RSCI 529 - Risk Management Tools
RSCI 531 - Industrial Approaches to Drug Discovery
RSCI 532 - Drug Development
RSCI 541 – Drug Development, Reimbursement and Marketing
RSCI 601 - Biomedical Commerce
RSCI 603 - Managing Complex Projects
RSCI 604 - Regulation in Asia
RSCI 605 - Managing Human Resources
RSCI 606 – Emerging Technologies
RSCI 608 - Regulation in Europe and the Americas
RSCI 607 -Research Design

Diverse other commitments to courses in different departments including School of Business, Engineering and Pharmacy that total less than 4 hours per course may not be listed.

Supervision or Cosupervision

Master of Science Students (Queen's)

1. G. Bakker (1980)
2. D. Bakker (1980)
3. J. Keane (1981)
4. J. Armstrong (1983)
5. C. Hammond (1987)
6. D. Gordon (1987)
7. D. Thomson (1991)
8. T. Liinamaa (1995)
9. K. Singh (1999)

Ph.D. Students (Queen's)

1. D. Bakker (1983)
2. D. Gordon (1990)
3. E. Smits (1993)
4. D. Thomson (1994)
5. A. Dupont (2001)
6. E. Melis (transferred, 1998)

Post-doctoral Fellows (Queen's)

1. S. Selbie (1990-1992)
2. J. Runciman (1994)
3. L. Kamibayashi (1994-1995)

Master of Science (USC) (management of core program)

- 16+ enrolled students (2001)
50 enrolled students (2002)
45 enrolled students (2003)
60 enrolled students (2004)
75 enrolled students (2005)
75 enrolled students (2006)
80+enrolled students (2007)
80+enrolled students (2008)
90+ enrolled students (2009-2020)

Regulatory Science DRSc (USC)(supervisor)

- Martin Solberg (2011)
Michael Jamieson (2011)
Susan Bain (2011)
Duane Mauzey (2012)
Tony Chan (2012)
Taranjit Singh (2012)
Ellen Whalen (2013)

Valerie Ramsey	(2013)
Haven McCall	(2013)
Neal Storm	(2013)
JoAnn Pfeiffer	(2013)
Chin-Wei Soo	(2014)
Neal Storm	(2014)
Patrick Dimapindan	(2014)
Kwabena Dankwah	(2015)
Bill Leitner	(2015)
Cesar Medina	(2015)
Nancy Smerkanich	(2015)
David Locke	(2015)
Caroline Mosessian	(2015)
Simone Turnbull	(2016)
Clare Elser	(2016)
Darin Oppenheimer	(2016)
Ali Rejaei	(2017)
Grant Griffin	(2017)
Terry Church	(2017)
Grant Dagliyan	(2018)
John Hartigan	(2019)
Penny Ng	(2019)
Aimee Greco	(2020)
Martha Kamrow	(2020)
Alexa Smith	(2020)
Lori Alquier	(2021)
Carolyn Wright	(2021)
Curtis Truesdale	(2021)
Sunita Babbar	(2021)
Mary Wilhelm	(2021)

DRSC (Supervisory committees)

Alicia Colarossi	(2018)
Jennifer Wiley	(2018)
Katherine St. Martin	(2020)
Lequina Myles	(2021)

20+ students in progress

Other programs

1. Kathy Knodel Thesis committee, EDD (2009) USC
2. Josh Page Thesis supervisor, MS Regulatory Affairs and Health Policy(2015) MCPHS

University Committees: Queen's

1980-1989:

Member; Advisory Committee for Selection of Dean, Arts and Science (1980)
Departmental Committee on Selection, Renewal and Tenure (1985)
Member; Advisory Committee, Queen's National Scholars Program (1985-1987)
Member and Scientific Officer; Graduate Research Committee, Faculty of Medicine (1985-1987)
Member; Steering Committee, Conference on Teaching and Learning (1986)
Member; Advisory Committee for Selection of Dean, Faculty of Medicine (1986-1987)

1990-1999:

Chairman; Queen's National Scholarship Program (1988-1991)
Member; Committee to Design the "First Year Experience" (1990-1991)
Member and Co-chair; Committee to Evaluate Policies Re. Teaching Assistants
Member; Faculty of Medicine Education Awards Committee (1990-1992)
Member; Search Committee for Headship in Urology (1992)
Member; Search Committee for Headship in Pharmacology (1992)
Member, Search Committee for Directorship of Animal Care (1996)
Chair, Grievance Panel re: Authorship and Intellectual Property (1996)
Member, Faculty of Medicine Promotions Committee (1996-1999)
Member, Neuromuscular Search Committee (1997-1998)
Member, Selection Committee for Headship of Department of Physiology (1997-1998)
Member, Appointments Committee, Department of Physiology (1998-1999)

University Committees: USC

Member, Advanced Technology Committee, 2002-2005
Member, ad hoc Committee on Animal Facilities, 2001-2002
Member, Financial Disclosure Committee, 2004- 2012
Chair, HSC Conflict of Interest in Research Committee, 2012-present
Member, University Advanced Technology Committee, 2006-2008
Co-chair, Education Section. Clinical and Translational Research Steering Committee, 2006-2008
Member, Human Subjects Steering Subcommittee, 2005-present
Member, Continuing Education Faculty Advisory Committee, 2008-2012
Chair, Technology-enhanced Learning and Distance Education Committee for Prizes and Grants, 2007
Member, USC School of Pharmacy Committee on Distance Learning Initiatives, 2009 to 2011
Member, USC School of Pharmacy Committee on Strategic Planning, 2009-present
Member, Steering Committee, Center for Technology and Innovation in Pediatrics 2010-2014
Member, Committee on Clinical Coordinator Training, 2011-2014

Member, COI Compliance Process Improvement Workgroup, 2011-2015
Member, University Corporate Research Group, 2011-2020
Chair, Conflicts of Interest in Research Committee at Health Sciences, 2012-present

Past/ Present Professional Memberships

Canadian Physiological Society (Councillor, 1987-1989; Secretary, 1991-1994; President, 1997-1998)
Canadian Federation of Biological Societies (Member, Board of Directors, 1991 – 1999)
Canadian Association for Neuroscience
Society for Neuroscience
American Association of Anatomists
American Association of Colleges of Pharmacy
American Association of Pharmaceutical Scientists
Drug Information Association
Regulatory Affairs Professionals Society
Orange County Regulatory Affairs Professionals Society
American Society for Quality
Society for Quality Assurance
Association of Graduate Regulatory Educators
National Academy of Inventors
Registered as a Nurse in Ontario #73-4338 7 and California # 575628

Scholarly and Professional Activities

- 1985 Symposium Organizer; Receptors in Skeletal Muscle: Changing Perspectives. Canadian Federation of Biological Societies, Toronto, Canada
Co-chairman Organizing Committee; The Control of Head Movement Satellite Symposium of the International Congress of Biological Societies, Vancouver, July, 1986
Member; Nominating Committee, Canadian Physiological Society
- 1986 Session Chairman, Winter Meeting, Canadian Physiological Society.
Organizer; IUPS Satellite Symposium, "The Control of Head Movement"
Co-editor of textbook: "The Control of Head Movement" published by Oxford University Press
Councillor; Canadian Physiological Society
Member; Grants Study Section, NIH, "Neurologic, Muscular, Perceptual and Cardiovascular Aspects of Falls and Gait Disorders in Elderly People"
- 1987 Member; Fellowships Committee (Ph.D.), Medical Research Council of Canada
Session chairman and member of organizing committee; Engineering Foundation Conferences, "The Development and Roles of Models"
Participant; National Defence College Course
- 1988 Associate Chairman, Fellowships Committees (Ph.D. and Health Sciences Professionals), Medical Research Council of Canada
- 1989-1993 Chairman; Fellowships Committee (Ph.D.) Medical Research Council of Canada
- 1990-1993 Member; Polanyi Prize Committee
- 1990-1992 Member; Canadian Federation of Biological Societies Committee on Equal Opportunities (1991-1994)
- 1991-1994 Secretary; Canadian Physiological Society
- 1991 Rapporteur - Workshop - Canada's Participation in the HFSP and Our Future Role in International Scientific Research

Scholarly and Professional Activities Continued:

- 1992-1993 Panel Member; Ontario Graduate Studentships
- 1992-1995 Member, Fellowships Committee - International Human Frontiers in Science Program
- 1993-1996 Member; Ontario Council of Graduate Studies Appraisals Panel
- 1993-1994 Policy Analyst; Industry Canada
- 1994-1995 Sabbatical experience as clinical research scientist, A.E. Mann Foundation for Scientific Research
- 1995 Symposium organizer and co-chair: Sensorimotor Transformations in the Nervous System, held at Queen's University, Kingston
- 1995 Workshop organizer and chair: Looking Ahead in Sensorimotor Control Big Questions for 2001, Workshop supported by Human Frontiers Science Program, held in Kingston, Canada
- 1996-1997 Invited Member, Biomedical Engineering Review Panel, Medical Research Council
- 1997-1998 Vice-President, Canadian Physiological Society
- 1998 Organizer and Chair - Conference for Research in Action and Perception, held in Kingston, Canada
- 1997-1998 President, Canadian Physiological Society
- 1998-2005 Member, Scientific Advisory Committee of the International Doctoral School in Biomedical Sciences and Engineering, Aalborg, Denmark
- 2000 Co-organizer, Mann Institute Symposium "Can We Make the Blind See?," Los Angeles California
- 2000 Co-organizer, Mann Institute Symposium "Putting the Brain in Command", Los Angeles, California
- 2000 Short-course Organizer and Program Chair, "Clearing Roadblocks in the New-Product Path" Irvine, CA , October 2000
- 2000 Short-course Organizer , "RA101", with Regulatory Affairs Professionals Society, Pasadena, CA, November 2000
- 2000 Short-course Organizer and Program Chair "The Regulation of Dietary

- Supplements and Functional Foods,” Pasadena, CA, November 2000
- 2000-2003 Advisory board- UCLA Extension Program
- 2000-2010 Advisory Board- School of Policy Planning and Development
- 2007-2010 Southern California Biomedical Council Subcommittee on Education/Training
- 2008, 2011 Referee and Site Reviewer, Arizona Science Foundation
- 2008-2011 Editorial Board of Medical Product Outsourcing
- 2009-2012 Medical Management Systems Council, (unpaid, arms length board for ethics oversight at Underwriters Laboratory)
- 2011-2014 Board of Directors, Drug Information Association
- 2013-2017 CTSI Regulatory Science Workgroup
- 2013- 2017 Board of Directors, Association of Graduate Regulatory Educators.
- 2013-2015 USP Regulatory and Compendial Science Consortium
- 2014-2015 Chair, Audit Committee, Drug Information Association, Board of Directors
- 2015 Secretary, Board of Directors, Association of Graduate Regulatory Educators
- 2015-2017 President, Association of Graduate Regulatory Educators
- 2018 Cofounder, Committee for International Pharmaceutical Regulatory Science Education Promotion
- 2018-present Member, FDA Pharmaceutical Science and Clinical Pharmacology Advisory Committee
- 2018-present Advisory Board/Steering Committee member, West Coast Consortium for Technology and Innovation in Pediatrics
- 2019-present Center of Excellence Directors’ Board, APEC-RHSC
- 2019-present Director, USC-APEC Center of Training Excellence in Medical Devices
- 2020 European Commission Expert Evaluator
- 2020 Member, Program Committee and Moderator, APEC Pilot Center of Excellence,

Regulatory Training Program, Shoonchunhyang University, Korea

2020- present Partner, Next Generation Global Health Supply Chain - Comprehensive Technical Assistance, USAID IDIQ with JSI Research & Training Institute.

2021 Member, Program Committee and Moderator, APEC Center of Excellence, Regulatory Training Program, Shoonchunhyang University, Korea

Past Referee/Consultant for Journals and Agencies:

Journals: Journal of Neurophysiology, Experimental Brain Research, Canadian Journal of Physiology and Pharmacology, Journal of Comparative Neurology, Journal of Morphology, Journal of Neuroscience, Journal of Biomechanics, Regulatory Focus; Medical Product Outsourcing (editorial board), Drug Information Journal, Therapeutic Innovation and Regulatory Science, Journal of Neural Engineering, Pharmaceutical Medicine, Frontiers in Regulatory Science

Agencies: Medical Research Council of Canada; National Institutes of Health; National Science Foundation; American Osteopathic Association; British Columbia Health Foundation; Glaxo Canada; Ontario Ministry of Health; ISC; Arizona Science Foundation; Society for Quality Assurance; European Commission; Advisory Committee member for US Food and Drug Administration

Invited Presentations and Lectures (1984 – Present, selection only):

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| April | 1984 | Organization of Primary Afferent Projections from Neck Muscles. University of Washington, Seattle, U.S.A. |
| October | 1984 | Unusual Forms of Mammalian Skeletal Muscle Architecture. Society for Neuroscience Satellite Conference, Tucson, U.S.A. |
| January | 1985 | Neck Muscle Architecture, Receptors and Movement. Neurosciences Institute, Rockefeller University, New York, U.S.A. |
| May | 1985 | Discussion Leader: Tensorial Approaches to Neck Muscles. National Institutes of Health, Washington, U.S.A. |
| June | 1985 | Chairman: Receptors in Skeletal Muscle: Changing perspectives. Canadian Federation for Biological Sciences, Toronto, Canada |
| July | 1985 | Structure and Function of Skeletal Muscle Receptors. Engineering Foundation Conference, Henniker, N.H., U.S.A. |
| October | 1985 | Biventer Cervicis: A Complex Muscle for a Complex Motor Task. Northwestern University, Chicago, U.S.A. |
| January | 1986 | Biological and Career Pressures on Women in Science. Forum on Women's Issues, Ontario Advisory Council of Women's Issues, Kingston, Canada. |
| May | 1986 | Achieving Excellence: Challenges for Faculty. Panel Presentation, Queen's University Council, Kingston, Canada. |
| May | 1986 | Moving Muscles: Studies in Neurophysiology. Canadian Science Writers' Association, Kingston, Canada. |
| July | 1986 | Structure and Function of Neck Muscles. IUPS Satellite Symposium, "The Control of Head Movement", Whistler, B.C. |
| April | 1987 | Basmajian Revisited: Muscle Physiology is Motor Physiology. Basmajian Award Lecture, Queen's University, Kingston. |
| May | 1987 | Problems for Women in Science. Panel Presentation. Science Writer's Association, Toronto, Canada. |
| July | 1987 | Architectural Specializations in Skeletal Muscle. Engineering Foundation Conference, Henniker, N.H., U.S.A. |

- August 1988 Do Excitatory Reflexes Exist in the Neck of the Alert Cat? ENA Symposium on Posture and Locomotion. Rheinfelden, Switzerland.
- August 1990 Organization of Natural Head and Neck Movements in the Cat. First World Congress of Biomechanics. San Diego, U.S.A.
- November 1990 Neurophysiology of Pain. Symposium on "Dealing with the Patient in Pain". Kingston, Canada.
- December 1990 Control of Head Movement: Is the Neck Another Limb? Dept. of Kinesiology, UCLA, Los Angeles, U.S.A.
- January 1991 Architectural and Functional Specializations Muscles: Complex Rules for Complex Muscles. Dept. of Zoology: Ohio State University, U.S.A.
- April 1991 Specializations of Fiber Architecture. Symposium on Functional Architecture of Skeletal Muscle; Forum in Cellular and Organ Biology, Chicago, U.S.A.
- September 1991 Sensory-Motor Organization of the Head Movement System. Symposium on "Muscle Afferents and the Spinal Control of Movement" to honour Y. Laporte, Paris, France.
- August 1993 Neuromuscular Control of the Two-Part Neck IUPS Symposium on Head Movement, Glasgow, U.K.
- April 1994 Muscles: Why Can't They be as Simple as the Textbooks Suggest? Southwestern University Medical School. Dallas, Texas.
- May 1994 The Anatomy of Muscle Architecture. Implications for Motor Control. 2nd International Symposium, The Medical Research Council Group in Sensory-Motor Physiology, Queen's University. Kingston, Ontario.
- July 1994 Mechanical Stability in Complex Muscles-Neural and Architectural Considerations. 2nd World Congress on Biomechanics Symposium on Muscle Mechanics. Amsterdam, Holland.
- July 1994 Skeletal Muscle: Structural Engineering Nightmare. Wright State University, Dayton, Ohio.
- December 1994 Postural Modifications of Neck-Muscle Synergies during Head Movement. Dept. of Kinesiology, UCLA, Los Angeles, U.S.A.

July	1995	1995 Structural and Biomechanical Factors Underlying Head-Neck Motor Function. Third International Symposium on the Head/Neck System, Vail, Colorado.
December	1996	Elements of Style in Muscle Architecture. Invited Lecture. Society for Comparative and Integrative Biology, Albuquerque, NM.
March	1998	Multiarticular Motor Systems: Lessons from the Head and Neck. Invited Lecture. Department of Electrical Engineering, University of Arizona, Tempe, Arizona.
November	1998	Animal Models of Motor Systems: Cautionary Tales from Studies of Head Movement. Invited Speaker. Peripheral and Spinal Mechanisms in the Neural Control of Movement, University of Arizona, Tucson, Arizona.
March	1999	Head Movement from Many Different Angles, Institute of Movement, University College London.
April	1999	Controlling the Multiarticulated Neck. Department of Biokinesiology and Physical Therapy, University of Southern California.
January	2000	Regulation of Dietary Supplements Moving Forward with Complementary Therapeutics, Continuing Education Program, USC
February	2000	Recruitment of Subjects: Similarities and Differences in Drug and Device Trials Foundations of Clinical research Trials, Advanced Series University of Southern California Short-course
March	2000	The Evolving Regulatory Climate for Dietary Supplements in the US. Hong Kong Business Mission on Herbal Products and Dietary Supplements, Los Angeles
November	2000	Health Claims on Supplements: Enforcement Actions of Federal Authorities. The Regulation of Dietary Supplements and Functional Foods, Pasadena CA
January	2001	Managing Biocompatibility Projects: Practical Applications MD&M West 2001 Conference, Anaheim, CA
December	2001	Ethics of Clinical Research: When does NIH and OHRP become involved? OCRA conference "Conducting Successful Clinical Trials under Good Clinical Practice Regulations to Facilitate the Product Approval Process"
December	2001	Preclinical Testing and Clinical Trials of BION Injectable Stimulators to

		Treat Disuse Atrophy, ITRI, Taiwan
November	2002	Clinical Trials in 2002: Trends and Issues, Novartis, NW Regional Meeting, Jackson Hole, Wyoming
October	2003	The ...omics Revolution. AOAC/FDA Joint Meeting, Irvine CA.
March	2004	Bioethics Biomedical Education Symposium. USC Marshall School of Business
August	2005	Overview of Drug Development. Amgen, Thousand Oaks
January	2005	Ephedra: What It Tells Us about Regulatory Systems. QSAD Annual meeting, Ojai ,CA
March	2006	Beyond the Codes: Practical Ethical Principles and Considerations for the Regulatory Professional, RAPS Horizons Conference, San Diego, 2006
April	2006	US Regulation of Generic Drugs and Dietary Supplements. Tiansin
July	2006	Training Methods and Outcomes in Regulatory Science. World Congress of Pharmacology, Beijing, China
October	2006	Graduate Training in Regulatory Affairs, Regulatory Affairs Career Forum, Minneapolis, MN
March	2007	Advanced Training and Recruitment in Regulatory Affairs. Horizons RAPS meeting, San Francisco, CA
April	2007	Tools for Assessment in TEL and Distance Learning, TEL_DL Faculty Forum, University of Southern California
August	2007	Good Laboratory Practices, City of Hope invited presentation
September	2007	New Regulations for US Dietary Supplements. China Life Sciences Summit, Beijing
February	2008	Moderator and speaker: Filling the Life-Sciences Industry's Pipeline, Human resources Conference, SCBC, Los Angeles, CA
July	2008	Participant, webinar, "The European Medical Device Directive: Upcoming Changes" FOI Teleconferences
July	2008	Speaker, "Risk management" American Society for Quality, Northridge CA
September	2008	Speaker, "Analysis of New Policies of American FDA" Fourth Annual China International Life Science Summit, Hangzhou, China
November	2008	Speaker, "Clinical trials for Generic Pharmaceuticals" and "505b(20 Applications for Novel Drugs and Novel Formulations, Xpo Pharm, Seoul, Korea.

- January 2009 Panel Organizer and Speaker, “Regulatory Strategies in Stem-cell and Nano Technology” Beckman Initiative For Macular Research/National Academies Conference. Irvine, CA
- February 2009 Speaker, “Dealing with Multiple Constituencies: A View from the Trenches” AHRPP Annual Meeting, Los Angeles, CA
- June 2009 Speaker, “Doctoral Education in Regulatory Science”, Orange Country Regulatory Affairs Annual meeting, Irvine CA
- October 2009 Speaker and Moderator, “US Regulatory System Update”, Beijing International Healthcare Industry Forum, Beijing, China
- November 2009 Speaker, “FDA Device Primer” Wonju Medical Technovalley Forum, Wonju, South Korea
- July 2009 Speaker, “US Regulation Landscape” Overcoming Commercial Barriers and Exploring Collaborative Opportunities in Regenerative Medicine. Scripps Research institute, La Jolla, July 27
- June 2010 Speaker, “Regulation of BCI Devices” , Telluride Neuromorphic CognitionWorkshop, Telluride, June 28
- July 2010 Speaker, “Stem Cells: From Bench to Clinic”, Scripps Research Institute, San Diego, July 27
- October 2010 Speaker, “Regulatory Science: a Key to Medical Device Commercialization”. Invited presentation at Yonsei University, October 6,
- 2010 Wonju, Korea Speaker, “Research & Development of Medical Devices in US: Regulatory and Quality Assurance”, Yonsei Medical Device Development and Promotion Center, Wonju, Korea
- March 2011 Speaker, “Regulatory Training and Coursework in Higher Education” Society for Quality Assurance, San Antonio, Texas, March 29-31, 2011
- September 2011 Speaker, “The US Regulatory System: An Update”, Development of Sino- American Collaboration in the Healthcare Industry, Sept 19, 2011
- Speaker, "FDA Regulations; An Update", International Cooperation and Development Forum of China Bio-Pharmaceutical Industry, Hangzhou, Sept 20, 2011
- Speaker, "FDA Regulations for Medical Devices", 2011 International Symposium, Challenges in Global medical Device Development, Wonju, South Korea, Sept 27, 2011
- November 2011 Speaker, "Recent Trends in FDA Regulation" 7th “FangYuan” Forum of the School of the International Pharmaceutical Business, China Pharmaceutical University, Nanjing, China, December 3, 2011

- December 2011 Speaker, "FDA Regulation of Over the Counter Drugs," China International Summit of OTC Industry Innovation and Development 2011 Boao Forum, Boao, China, December 4, 2011
- February 2012 Moderator, CDRH Top Headquarter Officials Discuss Product Clearances and Quality System Compliance for 2012, MD&M Show
- October 2012 Keynote Speaker, Today's Compliance and Regulatory Challenges OCRA-SDRAN Annual Joint Meeting, San Diego CA
- December 2012 Speaker, Generic Drugs; FDA Approval Process; Regulatory Science Invited Speaker, San Kyon Kwang University, Suwan, South Korea
- September 2013 Invited Speaker, Regulatory Trends and Education , Keio University, Tokyo Japan
Invited speaker, The US Regulatory System: An Update, SKKU, Seoul, Korea
Invited speaker, Global regulatory Environment and Market Access, Tianjin International Joint Academy of Biotechnology and Medicine/Tianjin FDA, Tianjin, China
Invited speaker, US Role in Emerging Markets, China Pharmaceutical University, Nanjing, China
- December 2013 Invited lecturer, Regulations of Drugs and Devices (14 hours), Tianjin University, Tianjin, China
Invited lecturer, International Regulations of Drugs: Non-CTD Countries, Peking University, Beijing, China
- June 2014 Invited speaker, OCRA, Regulatory Science and You, OCRA, Irvine, California
- September 2014 Course series, Quality and Audits, Tianjin-Binhai FDA headquarters, Binhai, China
- May 2015 Supervision Measures of Biopharmaceutical Innovation in China and US, China-US Biopharmaceutical Innovation Collaboration Forum , Los Angeles, CA

January	2016	Regulatory Science: Are we Coming of Age? San Diego Regulatory Affairs Network, Torrey Pines, CA.
July	2016	Regulatory Management of Neuroadaptive Technologies National Center for Adaptive Neurotechnologies, Albany NY
August	2016	Regulatory Science and Quantitative Drug Development Tools World Conference on Pharmacometrics, Brisbane, Australia
November	2016	Herbal products in the US: Food, Drug, or Dietary supplement? China Pharmaceutical University, Nanjing, China
April	2017	Overview of Medical Device Regulations Pathway to market Postmarket Regulations and Inspections IIT Madras Five-day course on Quality Systems University of Addis Ababa, Ethiopia
June	2017	Medical Products to Market Biotech Leaders Academy, Los Angeles
July	2017	Regulatory Management of Neuroadaptive Technologies National Center for Adaptive Neurotechnologies, Albany NY
October	2017	2017 Updates: Real World Evidence and Pharmacometrics SKKU-USC Joint Seminar Program, SKKU, Suwon South Korea
October	2017	2017 FDA Updates: Quality Initiatives Keio-USC Symposium, “Regulatory Update in the US and Japan” Keio University, Tokyo, Japan
October	2017	Evidence for Product Commercialization: How do we introduce real-world data? SHFDA CMDEC-USC Symposium, Shanghai, China
October	2017	USC Regulatory System updates: 2017: Generic Drugs CPU-USC Symposium, China Pharmaceutical University, Nanjing, China
November	2017	US Regulatory System Updates:2017 Peking University-USC Symposium, Peking University, Beijing, China
November	2017	Compounding Drugs for Clinical Trials. IND Workgroup Webinar

April	2018	through UTSW Evolution of Regulatory Science: US Academic Perspective. Utrecht University Symposium, Utrecht
July	2018	Regulatory Writing Short-course, Zimmer, Warsaw, IN.
August	2018	Regulatory Science at USC, APEC RHSC meeting, Brisbane Australia
September	2018	Crossing the Valley of Death: Moving Products toward Commercialization and Clinical Practice. CLINAM Summit, Basel Switzerland The Great Divide: Meeting Need for Regulatory Competence in Academia versus Industry. CLINAM Summit, Basel Switzerland
November	2018	Regulation versus Reimbursement: Can these be divorced? 2018 Asia Pacific Workshop on Social and Administrative Pharmacy. Taipei Taiwan Harmonization of Regulatory Science. Lecture to students and faculty at China Medical University Taichung, Taiwan US FDA: Changes and Issues. Lecture to students and faculty at China Medical University, Taichung, Taiwan Unique Device Identification. Lecture to 30 members of Shanghai FDA
January	2019	APEC Initiatives in Regulatory Training. Webinar, AGRE
May	2019	FDA Regulatory Priorities. University of Copenhagen, Denmark FDA Structure and Roles, University of Copenhagen, Denmark
October	2019	2019 US Regulatory Updates, Keio University, Japan
October	2019	Recent changes of medical device regulations in the US, and perspectives from academia and industry. PMDA, Tokyo, Japan
October	2019	The USC Regulatory Science Program . Taiwan Center for Drug Evaluation Taipei, Taiwan
October	2019	US Regulatory Updates. TsRAP and National Taiwan University, Taipei, Taiwan
October	2019	US Regulatory Updates. NMPA, Beijing, China

February	2020	From Bench to market: An overview; Classifying devices and choosing indications; Regulatory requirements for devices and IVDs; Premarket notifications: the 510(k) options; Logistical management of clinical trials; Quality management; Promoting product before and after launch; What are codes and why it matters. National Cheng Kung University, Tainan, Taiwan.
October	2020	Combination Products. Tsinghua University, Beijing, China
March	2021	Emerging Trends in medical Device Regulation. Nirma University, India

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Grants

Until 1999 (Canada):

In Canada, I was funded continuously by the Medical Research Council of Canada since I began my career as an Assistant Professor in the late 1970s. Most recently, in the period from 1994-1999, I was the Director of the MRC Research Group in Sensory-Motor Physiology, funded at a level of about 5 million dollars (direct costs, no investigator salaries) over a 5 year period.

1999-2008 (USC):

My position until July 2008 was split between directing the regulatory and clinical activities of the Alfred E Mann Institute and directing the Regulatory Science Program in the School of Pharmacy. This unusual position did not require that I apply for grant funds in the usual way, as a Principal Investigator of a single-investigator grant. Our experimental work was funded in a group configuration—either as a part of the core activities of the Mann Institute, or as part of larger group grants for the development of major medical device projects. Most of the writing that I did was contained in confidential business development and regulatory dossiers. Fifty percent of my salary was paid by the Alfred E Mann Institute and 45% of that 50% was covered by grants, below.

2009-2020 (USC):

I directed the Regulatory Science programs in the School of Pharmacy and was the founding Chair of the Department of Regulatory and Quality Sciences. This group of programs includes a doctoral program, three master's programs, an undergraduate major and minor, and 5 certificate programs, principally funded through tuition revenue rather than grants.

Recent Activities related to Grant-funded Research

Injectable sensors for control of FES Coinvestigator, Director of Regulatory Core (funded)	NIH \$917,595	6-1-01 to 5-31-08
Bion Rx of neuromuscular dysfunction Scientist, Interface Technology thrust (funded)	NIH \$9,322,983	5-1-02 to 30-07-08
Engineering Research Consortium Scientist, Animal Trials	NSF \$10,000,000	8-1-03 to 30-07-10
Clinical and Translational Science Initiative, NIH, \$67,113,902 Director, Regulatory Knowledge and Support Group		7-1-10 to 6-30-15
USC Tobacco Center of Regulatory Science for Vulnerable Populations Coinvestigator, Research Training and Education Core	NIHP50 \$3,977,518	7-1-13 to 6-30-18
Consortium for Technology Innovation in Pediatrics Member Advisory Board and Regulatory Expert	FDA \$6,600,000	2018-2023

2020-present (USC)

I currently direct the DK Kim International Center for Regulatory Science and the USC-APEC Center of Training Excellence in Medical Devices. Goals for these activities include developing opportunities for international students in graduate studies to take part in regulatory training opportunities at USC; bringing international scholars and fellows to the university as scholars-in-residence; fostering outreach activities to underserved economies and communities; and to participate in global educational programs to advance capacity in regulatory, clinical and quality sciences; conducting research related to international regulatory policy and harmonization; educating regulators and others as an APEC Center of Training Excellence.

Activities Related to Teaching

The MS (Regulatory Science) has grown over a decade and has graduated more than 700 students. Some of these educational activities have recently been brought under the wing of the International Center for Regulatory Science and others are part of the normal training opportunities of the department. At least forty courses are offered each year, some across all three terms.

USC Regulatory Science is also an APEC LSIF Center of Training Excellence in Medical Devices.

Advisory Boards

Editorial Board of Medical Product Outsourcing	2008-2010
Medical Management Systems Council	2009-2012
AACP Graduate Education SIG Curriculum Task Force	2013-2015
ASQ TAG 176 Subcommittee	2012-2014
USP Knowledge, Education and Training on Regulatory and Compendial Science Advisory Group	2013-2015
Drug Information Association Board of Directors	2012 to 2015
AGRE Board of Directors, President	2015 to 2017
FDA Advisory Committee, Pharm. Science and Clinical Pharmacy	2018 to present
West Coast Consortium for Technology and Innovation in Pediatrics	2019 to present